

K970620

SUMMARY OF SAFETY EFFECTIVENESS

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I. General Provisions

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Common or Usual Name: PTA Balloon Catheter

Proprietary Name: Opta5™ PTA Balloon Catheter

II. Name of Predicate Devices

- Cordis Opta5 PTA Balloon Catheter
- Cordis Nylex Angiographic Catheter
- Cordis Ducor PTA Catheter
- Meditech Ultra-Thin Balloon Catheter

III. Classification

Class II

IV. Performance Standards

Performance standards have not been established by the FDA under section 514 of the Food, Drug and Cosmetic Act.

V. Intended Use and Device Description

The Opta5 PTA balloon catheters is intended to dilate stenoses in iliac, femoral, ilio-femoral, popliteal infra popliteal and renal arteries, and for treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae

The Cordis Opta5 PTA balloon catheter is a coaxial design with a distal inflatable balloon. Two radiopaque marker bands indicate the dilating section of the balloon and aid in balloon placement.

The working pressure range for the balloon is between the nominal size pressure and the rated burst pressure. All balloons distend to sizes above the nominal size at pressures greater than the nominal pressure.

The balloon lumen is used to inflate and deflate the balloon. The nominal balloon size is printed on the hub.

The injectate lumen is used to track the catheter over a prepositioned guidewire or to inject contrast medium and/or saline. The maximum injection pressure is 500 psi. The compatible guidewire size, catheter shaft French size and catheter length are printed on the hub. The radiopaque marker bands indicate the stated nominal length of the balloon. The tip length of the long tip version is approximately 10cm and is provided with side holes.

VI. Biocompatibility

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All materials used in the Opta5 PTA balloon catheter are biocompatible.

VII. Summary of Substantial Equivalence

The Cordis Opta5 PTA balloon catheter and the referenced current Cordis Opta5 PTA balloon catheter, Cordis Ducor PTA catheter, Cordis Nylex angiographic catheter and Meditech Ultra-Thin balloon catheter are similar in their basic design, construction, indication for use and performance characteristics.